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5.0 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Osteotech's PLEXUR M 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of PLEXUR M is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device(s) .

Sponsor/ Manufacturer	Osteotech, Inc. 51 James Way Eatontown, NJ 07724
Contact	Chris Talbot Osteotech, Inc. 51 James Way Eatontown, NJ 07724 Ph: (732) 542-2800 Talbot@osteotech.com
Date Prepared	November 30, 2007
Proposed Class	II
Proprietary Name	PLEXUR M
Common Name	Bone void filler
Classification Name	Resorbable calcium salt bone void filler device
Regulation Number	21 CFR 888.3045
Product Code	MQV

Predicate Device PLEXUR M is substantially equivalent, for the purpose of this 510(k), to other devices that have received 510(k) clearance for similar indications for use.

Intended Use PLEXUR M is intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects

created from traumatic injury to the bone. PLEXUR M is resorbed/remodeled and is replaced by host bone during the healing process.

Device Description

PLEXUR M is a bone void filler product that contains, as a key constituent, processed human bone particles that are mixed with resorbable/biodegradeable non-tissue components. It is intended to be heated at the time of use, whereupon it becomes moldable, thus allowing the surgeon to pack it into the implant site or shape it to accommodate variations in the geometry and size of the particular implant site. As it cools down, the PLEXUR M returns to its normal hardened/rigid state and remains this way at body temperature. The surgeon may further shape, cut or grind PLEXUR M in the hardened state using conventional surgical instruments.

PLEXUR M is packaged/provided for single use in a sterile form. PLEXUR M is resorbed/remodeled and is replaced by host bone during the healing process. A compact, single use heater is available as a means to heat the PLEXUR M at the time of use to make it pliable. Osteotech is seeking approval of this single use heater as part of this 510(k) submission. Alternatively, PLEXUR M may be heated in a water bath.

Performance Data

The results of studies in animals showed that PLEXUR M supports bone ingrowth and new bone formation.

Viral Inactivation

In the production of PLEXUR M, the allograft bone is subjected to processing steps that have been shown to inactivate viruses, including HIV, hepatitis B and C and CMV.

Technical Comparison

PLEXUR M is substantially equivalent to one or more of the predicate devices with respect to materials. PLEXUR M contains human allograft bone tissue, as does one or more of the predicate devices. PLEXUR M also contains resorbable polymer of the same

type as those in one or more of the predicate devices. Also, like one or more of the predicate devices, PLEXUR M is provided sterile in various sizes that, upon heating (using a compact, single use sterile heater to be marketed by Osteotech), is made moldable and can be cut or shaped by the user into various shapes or sizes. It may be further shaped by the surgeon in its hardened state using conventional surgical instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Osteotech, Inc.
% Mr. Christopher Talbot
Director of Regulatory Affairs
51 James Way
Eatontown, New Jersey 07724

MAR - 3 2008

Re: K073405
Trade/Device Name: PLEXUR M Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: November 30, 2007
Received: December 4, 2007

Dear Mr. Talbot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number: K073405

Device Name: PLEXUR M

Indications for Use: PLEXUR M is intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. PLEXUR M is resorbed/remodeled and is replaced by host bone during the healing process.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073405